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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/717,743   | 11/21/2000  | Rajesh Ranganathan   | 01997/521003        | 1951             |
| 21559  | 7590        | 03/22/2005           | EXAMINER            |                  |
| CLARK & ELBING LLP<br>101 FEDERAL STREET<br>BOSTON, MA 02110 |             |                      | WOITACH, JOSEPH T   |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1632                 |                     |                  |

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                   |                    |
|------------------------------|-------------------|--------------------|
| <b>Office Action Summary</b> | Application No.   | Applicant(s)       |
|                              | 09/717,743        | RANGANATHAN ET AL. |
|                              | Examiner          | Art Unit           |
|                              | Joseph T. Woitach | 1632               |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 December 2004.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3,5,23 and 24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 23 and 24 is/are allowed.  
 6) Claim(s) 1,3 and 5 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 11/21/2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

This application filed November 21, 2000, is a continuation in part of application 09/559,622, filed April 27, 2000, which claims benefit to 60/131,149, filed April 27, 1999.

Applicants' amendment filed December 20, 2004, has been received and entered. Claims 2, 4, 6-22 have been canceled. Claims 1, 23 and 24 have been amended. Claims 1, 3, 5, 23 and 24 are pending.

### ***Election/Restriction***

Election was made without traverse in Paper No. 11. Claims 1, 3, 5 23 and 24 are currently under examination as they are drawn to a substantially pure nucleic acid sequence encoding a serotonin-gated anion channel.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

Claim 1 is objected to because of the following informalities:

The claim has been amended to recite specific hybridization conditions, in particular specific temperatures used for hybridization and washing. However, the temperatures recited in

the claims are set forth as "45EC" and "65EC". Correction to recite "45°C" and "65°C" is suggested.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Claim 1 has been amended to recite specific hybridization conditions however, there is no literal support in the instant specification for the specific conditions recited in the claim. In particular, the first wash is done with 1% SDS, not about 1%, and the second wash uses 0.1% SDS, not 1%. The specification provides two specific conditions for hybridization, high and low stringencies, however neither indicate that conditions recited in claim 1.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly

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conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claims 1, 3, 5 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants summarize the basis of the rejection and the requirements of written description under 35 USC 112, first paragraph citing relevant case law (pages 4-5). Applicants note the amendment to the claims (page 6) and evidence presented in the instant specification (pages 6-7), and argue that "even though the claimed invention is exemplified by a single serotonin anion channel" one of skill in the art would readily recognize that this sequence is illustrative and includes any functional serotonin-gated anion channel that is structurally related as defined by its ability to hybridize under the conditions now recited in claim 1 (page 6). More specifically, it is noted that in Lilly the court held that written description of a genus of DNA

may be achieved by a “recitation of structural features common to members of the genus” (page 7 and Lilly, 1406). Pointing to Example 9 of the written description guidelines published by the office, Applicants argue that the facts of the instant application fall squarely within the guidelines (page 8). See Applicants’ amendment, pages 4-9. Applicants’ arguments have been fully considered, but not found persuasive.

Initially, it is noted that support for the hybridization conditions recited in the claim is found on page 35, and that they are not exactly the conditions set forth for under high stringency conditions as noted above. However, even if the claim was amended, the issue remains to whether the hybridization conditions describe a physical characteristic that is shared by all the members of the genus. In this case the ability to hybridize to SEQ ID NO: 2 at any condition fails to provide any relevant structural information that results in the functional limitations. For example, a one base pair difference that results in a truncated or no protein at all would clearly hybridize, however these would clearly not meet the functional limitations of the claim.

Alternatively, altering the coding sequence to the degenerative codons would result in a sequence that produces exactly the same protein as SEQ ID NO: 2, however would not hybridize. So clearly hybridization conditions fail to describe a genus. At most it describes a genus of sequences that can hybridize to SEQ ID NO: 2 which as illustrated above is much larger than the genus of sequences that have a specific functional characteristic. The findings of Lilly concern a description of structural properties relevant to the functional properties, and in this case which hybridization fails to do. As acknowledged by Applicants, only one species is disclosed. This is important because as noted by Applicants, this sequence encodes a unique anion channel not previously described in the art of record. Comparison of the sequences in the prior art and the

instant sequence indicates that they share significant structural similarities, i.e. various external/internal and transmembrane domains, however the ion selectivity of the single species disclosed is unique to those in the prior art. There is nothing about the hybridization conditions that relate to the structural uniqueness of this new family member of HT/serotonin gated channels. In addition, dependent claims set forth that it is selective for chloride ions and that it is MOD-1, however the specification fails to provide any particular description or guidance that would lead the artisan to know what member of the genus of claim 1 is specifically a chloride ion channel or what uniquely defines a sequence as a “MOD-1” channel. As noted previously, the definition provided by the specification of the invention of MOD-1 taught is described as a serotonin-gated ion channel (page 4; line 8), and includes other forms of the channel including sequences from any animal sources, and a variant or mutant of the 5HT receptor (pages 5-7). Moreover, the only species disclosed is only permeable to chloride, not any anion as encompassed by the instant claims. As discussed above, hybridization will result in the identification of sequences that share homology, however it is only upon testing the functional properties of these sequences that can hybridize can one determine whether the encoding sequence meets the functional limitations set forth in the claim.

The instant disclosure provides a single sequence and fails to describe all the potential serotonin-gated anion channels that exist or could be made, or even set forth what is specifically encompassed by the term “MOD-1”. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Again, possession may be shown by actual reduction to practice, clear depiction of the

invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). Naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material (*Lilly*), and adequate written description under 35 USC 112, first paragraph, requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). While it is not disputed that one could use the disclosed sequence to identify other related sequences and that the encoded protein sequences could be assayed for the desired properties, the fact that the encoded sequence would have to be further characterized supports that written description requirement has not been satisfied.

For the reasons above and of record, it is maintained that the disclosure of one species termed MOD-1 fails to adequately describe other MOD-1 from other species, or more generally define a serotonin-gated anion channel encompassed by the claims. Therefore, only the recited SEQ ID NOs provided in the instant disclosure meet the written description provision of 35 U.S.C. §112, first paragraph.

***Conclusion***

Claims 23 and 24 are allowed. The remaining claims are free of the art of record because the prior art failed to describe a serotonin gated channel that selectively permits passage of anions as required by the instant claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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